Aqautic Animal Health Standards Commission Report

October 2007

CHAPTER 1.4.2.

GUIDELINES FOR IMPORT RISK ANALYSIS

Article 1.4.2.1.

Introduction

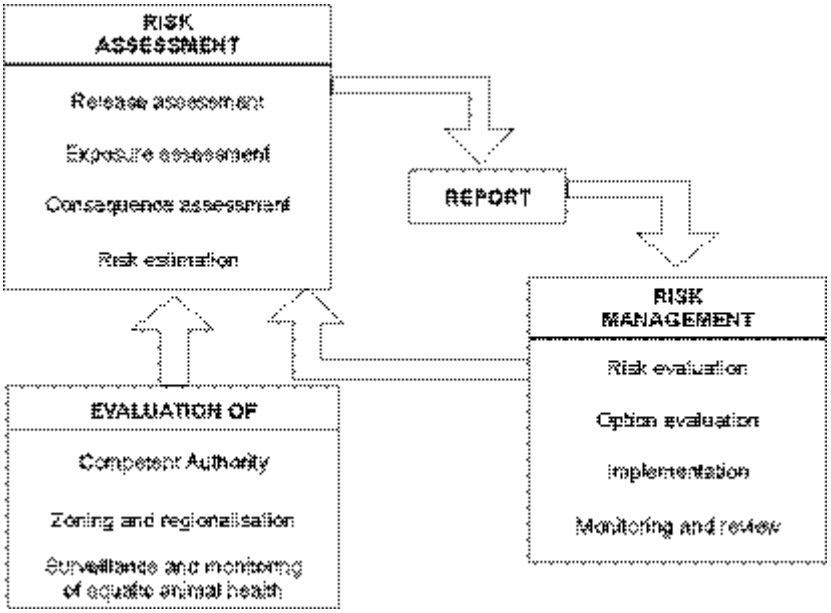
An import risk analysis begins with a description of the *commodity* proposed for import and the likely annual quantity of trade. It must be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the risk estimate, it may not be readily available, particularly where such trade is new.

Hazard identification is an essential step that must be conducted before the *risk assessment.*

The *risk assessment* process consists of four interrelated steps. These steps clarify the stages of the *risk assessment,* describing them in terms of the events necessary for the identified potential *risk(s)* to occur, and facilitate understanding and evaluation of the conclusions (or 'outputs'). The product is the *risk assessment* report, which is used in *risk communication* and *risk management.*

The relationships between *risk assessment and risk management processes* are outlined in Figure 1.

*Fig. 1. **The relationship between risk assessment and risk management processes***



Article 1.4.2.2.

Hazard identification

Hazard identification involves identifying the pathogenic agents that could potentially produce adverse consequences associated with the importation of a *commodity*.

The *hazards* identified would be those appropriate to the species being imported, or from which the *commodity* is derived, and which may be present in the *exporting country*. It is then necessary to identify whether each *hazard* is already present in the *importing country*, and whether it is an *OIE-listed disease* or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

Hazard identification is a categorisation step, identifying biological agents dichotomously as *hazards* or not *hazards*. The *risk assessment* should be concluded if *hazard identification* fails to identify *hazards* associated with the importation.

The evaluation of the *Competent Authorities*, surveillance and control programmes, and *zoning* and regionalisation systems are important inputs for assessing the likelihood of *hazards* being present in the *aquatic animal*population of the *exporting country*.

An *importing country* may decide to permit the importation using the appropriate sanitary standards recommended in the *Aquatic Code*, thus eliminating the need for a *risk assessment*.

Article 1.4.2.3.

Principles of risk assessment

1. *Risk assessment* should be flexible in order to deal with the complexity of real-life situations. No single method is applicable in all cases. *Risk assessment* must be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each *disease*, detection and surveillance systems, exposure scenarios and types and amounts of data and information.

2. Both *qualitative* and *quantitative* risk assessment methods are valid. Although quantitative analysis is recognised to provide deeper insights into a particular problem, qualitative methods may be more relevant when available data are limited as is often the case with aquatic species.

3. The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well documented and supported with references to the scientific literature and other sources, including expert opinion.

4. Consistency in *risk assessment* methods should be encouraged and *transparency* is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.

5. *Risk assessments* should document the *uncertainties*, the assumptions made, and the effect of these on the final *risk* estimate.

6. *Risk* increases with increasing volume of *commodity* imported.

7. The *risk assessment* should be amenable to updating when additional information becomes available.

Article 1.4.2.4.

Risk assessment steps

1. Release assessment

Release assessment consists of describing the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) a *hazard* into a particular environment, and estimating the likelihood of that complete process occurring. The release assessment describes the likelihood of the 'release' of each of the *hazards* under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the release assessment are:

a) Biological factors

- Species, strain or genotype, and age of *aquatic animal*
- Strain of agent
- Tissue sites of infection and/or contamination
- Vaccination, testing, treatment and quarantine.

b) Country factors

- Incidence/prevalence
- Evaluation of *Competent Authorities*, surveillance and control programmes, and *zoning* systems of the *exporting country*.

c) Commodity factors

- Whether the *commodity* is alive or dead
- Quantity of *commodity* to be imported
- Ease of contamination
- Effect of the various processing methods on the pathogenic agent in the *commodity*
- Effect of storage and transport on the pathogenic agent in the *commodity*.

If the release assessment demonstrates no significant *risk*, the *risk assessment* does not need continue.

2. Exposure assessment

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of humans and aquatic and terrestrial animals in the *importing country* to the *hazards* and estimating the likelihood of these exposure(s) occurring~~, and of the spread or establishment of the *hazard*~~.

The likelihood of exposure to the *hazards is* estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure, and the number, species and other characteristics of the human, *aquatic animal* or terrestrial animal populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

a) Biological factors

- Presence of potential vectors or intermediate hosts
- Genotype of host
- Properties of the agent (e.g. virulence, pathogenicity and survival parameters).

b) Country factors

- *Aquatic animal* demographics (e.g. presence of known susceptible and carrier species, distribution)
- Human and terrestrial animal demographics (e.g. possibility of scavengers, presence of piscivorous birds)
- Customs and cultural practices
- Geographical and environmental characteristics (e.g. hydrographic data, temperature ranges, water courses).

c) Commodity factors

- Whether the *commodity* is alive or dead
- Quantity of *commodity* to be imported
- Intended use of the imported *aquatic animals* or *products* (e.g. domestic consumption, restocking, incorporation in or use as *aquaculture* feed or bait)
- Waste disposal practices.

If the exposure assessment demonstrates no significant *risk*, the *risk assessment* should conclude at this step.

3. Consequence assessment

Consequence assessment consists of identifying the potential biological, environmental and economic consequences. A causal process must exist by which exposures to a *hazard* result in adverse health, environmental or socio-economic consequences. Examples of consequences include:

a) Direct consequences

- *Aquatic animal infection*, *disease,* production losses and facility closures
- Adverse, and possibly irreversible, consequences to the environment

- Public health consequences.

b) Indirect consequences

- Surveillance and control costs
- Compensation costs
- Potential trade losses
- Adverse consumer reaction.

4. Risk estimation

Risk estimation consists of integrating the results of the release assessment, exposure assessment, and consequence assessment to produce overall measures of *risks* associated with the *hazards* identified at the outset. Thus risk estimation takes into account the whole of the *risk* pathway from *hazard* identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

- The various populations of *aquatic animals* and/or estimated numbers of *aquaculture establishments* or people likely to experience health impacts of various degrees of severity over time
- Probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates
- Portrayal of the variance of all model inputs
- A sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output
- Analysis of the dependence and correlation between model inputs.

Article 1.4.2.5.

Principles of risk management

1. *Risk management* is the process of deciding upon and implementing measures to achieve the Member's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of *disease* incursions and their consequences and its desire to import *commodities* and fulfil its obligations under international trade agreements.

2. The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management.* The application of these *sanitary measures* should be in accordance with the intentions of the standards or other recommendations of the SPS Agreement.

Article 1.4.2.6.

Risk management components

1. Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the Member's appropriate level of protection.

2. Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the *risk* associated with an importation in line with the Member's appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses n technical, operational and economic factors affecting the implementation of the *risk management* options.

3. Implementation - the process of following through with the *risk management* decision and ensuring hat the *risk management* measures are in place.

4. Monitoring and review - the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

Article 1.4.2.7.

Principles of risk communication

1. *Risk communication* is the process by which information and opinions regarding *hazards* and *risks* are gathered from potentially affected and interested parties during a *risk analysis*, and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision makers and interested parties in the *importing* and *exporting countries.* It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.

2. A *risk communication* strategy should be put in place at the start of each *risk analysis.*

3. The *communication of risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

4. The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic aquaculturists, recreational and commercial fishermen, conservation and wildlife groups, consumer groups, and domestic and foreign industry groups.

5. The assumptions and *uncertainty* in the model, model inputs and the risk estimates of the *risk assessment* should be communicated.

6. Peer review of *risk analyses* is an essential component of *risk communication* for obtaining a scientific critique aimed at ensuring that the data, information, methods and assumptions are the best available.